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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,732	09/26/2007	Michael D. Dake	13720-105071US2	3155

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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	**PAPER NUMBER**
1645	

NOTIFICATION DATE	DELIVERY MODE
06/11/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/591,732	DAKE ET AL.	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-146,149 and 150* is/are pending in the application.

4a) Of the above claim(s) *56-63,74-76 and 119-145* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-55,64-73,77-118,146,149 and 150* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/17/08, 1/24/08, 3/24/08, 10/7/08, 7/6/09, 7/27/09, 2/16/10*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 51-55, 64-73, 77-118, 146, 149 and 150, in the reply filed on March 16, 2010 is acknowledged. Claims 56-63, 74-76 and 119-145 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 16, 2010. Claims 147 and 148 have been cancelled. Claims 51-146, 149 and 150 have been amended. Claims 51-55, 64-73, 77-118, 146, 149 and 150 are currently under examination.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on January 17, 2008, January 24, 2008, March 24, 2008, October 7, 2008, July 6, 2009, July 27, 2009 and March 16, 2010 are in compliance with the provisions of 37 CFR 1.97 and has been considered. An initialed copy is attached hereto.

Specification Objections

3. This application fails to comply with the requirements of 37 C.F.R. 1.821-1.825 because it contains sequences that are not identified. For example, pages 11, 13, and 14 contain sequences that are not identified. Appropriate sequence identifiers should match the sequence listing and the computer readable form (CFR) submitted with the

application. Applicant is required to review the specification for unidentified sequences. Identification of these sequences is required.

4. The use of the trademarks NeutrAvidin (page 24) and Cetaphil (page 32) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

5. Claim 53 is objected to because of the following informalities: The word "in" following "51" needs to be deleted. Appropriate correction is required.

6. This application fails to comply with the requirements of 37 C.F.R. 1.821-1.825 because it contains sequences that are not identified. For example, claim 93 contain sequences that are not identified. Appropriate sequence identifiers should match the sequence listing and the computer readable form (CFR) submitted with the application. Identification of these sequences is required.

7. Claims 52 and 108 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 52 is substantially identical to claim 51 and claim 108 is substantially identically to claim 78.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 51 and 116-118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 118 is rendered vague and indefinite by the use of the phrase “cell-encapsulating device”. It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. What constitutes a “cell-encapsulating device”? As written, it is impossible to determine the metes and bounds of the claimed invention.

9. Claim 104 recites the limitation "in which the polyalkyleneimine is a polyethyleneimine" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 51-55, 63-73, 77-85, 110, 149 and 150 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 78-85, 88 and 90-97 of copending Application No. 10/591,485 ('485); PG Pub 2008/0200373 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '485 claims are drawn to a method of topically applying to the skin or epithelium of a subject, a composition comprising a carrier which has a polymeric backbone having positively charged branching groups and a biologically active protein, wherein the carrier and the biologically active protein associate non-covalently. The biologically active protein of the '485 application is a botulinum toxin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 51, 54, 55, 77, 80-87, 97, 98, 149 and 150 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 10 and 11 of copending Application No. 12/647,677 ('677). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '677 claims are drawn to a method of administering botulinum toxin to achieve a therapeutic or cosmetic effect to an individual in need thereof comprising administering a composition comprising a positively charged carrier comprising a charged backbone, wherein the positively charged carrier is non-covalently associated with the botulinum toxin. Moreover, claim 10 of the '677 application recites that the treatment is for wrinkles, which one of ordinary skill in the art would considered a topical application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

> by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

12. Claims 51-55, 64-73, 77-118, 146, 149 and 150 are rejected under 35 U.S.C. 102(e) as being anticipated by Waugh et al. (U.S. 2004/0220100 A1; filing date: 7/21/00)

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The rejected claims are drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent.

Waugh et al. disclose a method for transdermal delivery of a composition comprising botulinum toxin (types A-G; naturally occurring, recombinant, modified and/or including fusion proteins) as the biologically active agent together with a carrier comprising a positively charged backbone with attached positively charged branching groups. The positively charged carrier is a polypeptide or nonpeptidyl polymer such as polyalkyleneimine (see abstract; paragraphs 0010 and 0043). Waugh et al. disclose that the positively charged backbone is a nonpeptidyl polymer such as a

polyalkyleneimine, having a molecular weight of from about 10,000 to about 2,500,000, from about 100,000 to about 1,800,000, and from about 500,000 to about 1,400,000 (see paragraph 0078). Waugh et al. disclose cosmetic compositions comprising a backbone having attached positively charged groups such as (Gly)n1-(Arg)n2, wherein n1 is an integer of from 0 to 20 and from 3 to about 5, and n2 is an odd integer of from 5 to 25 and about 7 to about 17, or TAT (HIV-TAT) domains. Waugh et al. further disclose that said positively charged backbone and groups are a polypeptide having the formula (gly)p-RGRD-DRRQRR-(gly)q or (gly)p-YGRKKRRQRRR-(gly)q (see paragraphs 0082-83). Moreover, Waugh et al. disclose that the compositions are administered in a combination procedure, which may involve either combining them in a composition, which is then administered to the subject, or administering them separately (see paragraph 0048). Waugh et al. disclose that the botulinum toxin is administered topically for transdermal delivery to skin-associated structures. The administration may be to the legs, shoulders, back including lower back, axilla, palms, feet, neck, groin, dorsa of the hands or feet, elbows, upper arms, knees, upper legs, buttocks, torso, pelvis, or any other part of the body where administration of the botulinum toxin is desired (see paragraph 0135). The compositions may be administered in the form of a skin patch or other dispensing device, including a controlled released device, a liquid, gel, cream or the like that contains the positively charged carrier (see paragraphs 0022 and 0138). Waugh et al. disclose that the botulinum toxin is prepared with saline and may be buffered (see paragraph 0137). The botulinum toxin is applied in a composition having a pH from about 4.5 to about 6.3 (see paragraph 0141). Waugh et al. disclose

that the positively charged backbone is a polylysine having a molecular weight of 70,000 to 150,000 and 150,000 to 300,000 and is in an amount of at least about 0.05% of the total carrier weight (see paragraphs 0083 and 0084).

13. Claims 51-55, 77, 80, 81, 86-93, 97-104, 110-115 and 118 are rejected under 35 U.S.C. § 102(e) as being anticipated by Waugh et al. (US 2003/0229034 A1; filing date: 6/21/01).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The rejected claims are drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent.

Waugh et al. disclose cosmetic compositions comprising Botulinum toxin (see paragraph 0082) and a backbone having attached positively charged groups such as $(Gly)_{n1}$-$(Arg)_{n2}$, wherein n1 is an integer of from 0 to 20 and from 3 to about 5, and n2 is an odd integer of from 5 to 25 and about 7 to about 17, or TAT (HIV-TAT) domains.

Waugh et al. further disclose that said positively charged backbone and groups are a polypeptide having the formula $(gly)_p$-RGRD-DRRQRR-$(gly)_q$ or $(gly)_p$-YGRKKRRQRRR-$(gly)_q$ (see paragraph 0033 and 0052). Waugh et al. disclose that the positively charged backbone is a polylysine having a molecular weight of 70,000 to 150,000 and 150,000 to 300,000 (see paragraphs 0053). Waugh et al. disclose that the backbone will often be a polymer of repeating units such as a polypropyleneamine and that the composition can comprise and saline as well as a buffer (see paragraphs 0047, 0098 and 0207). Moreover, Waugh et al. disclose that the compositions can be formulated to provide mixtures suitable for topical (to the skin) administration and can take the form of liquid, capsules creams, ointments and lotions and can be use alone or in combination with other suitable components in unit-dose or multi-dose containers, such as ampules and vials as well as a sustained-release formulation (see paragraphs 0098 and 0102-105).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 64-73, 78, 79, 82-85, 94-96, 105-109, 116, 149 and 150 are unpatentable over Waugh et al. (US 2003/0229034 A1; filing date: 6/20/01) as applied to claims 51-

55, 77, 80, 81, 86-93, 97-104, 110-115 and 118 above in view of Hanin (U.S. Patent No. 6,688,311 B2; filing date: 3/14/02).

The rejected claims are drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent.

Waugh et al. disclose cosmetic compositions comprising Botulinum toxin (see paragraph 0082) and a backbone having attached positively charged groups such as $(Gly)_{n1}$-$(Arg)_{n2}$, wherein n1 is an integer of from 0 to 20 and from 3 to about 5, and n2 is an odd integer of from 5 to 25 and about 7 to about 17, or TAT (HIV-TAT) domains. Waugh et al. further disclose that said positively charged backbone and groups are a polypeptide having the formula $(gly)_p$-RGRD-DRRQRR-$(gly)_q$ or $(gly)_p$-YGRKKRRQRRR-$(gly)_q$ (see paragraph 0033 and 0052). Waugh et al. disclose that the positively charged backbone is a polylysine having a molecular weight of 70,000 to 150,000 and 150,000 to 300,000 (see paragraphs 0053). Waugh et al. disclose that the backbone will often be a polymer of repeating units such as a polypropyleneamine and that the composition can comprise and saline as well as a buffer (see paragraphs 0047, 0098 and 0207). Moreover, Waugh et al. disclose that the compositions can be formulated to provide mixtures suitable for topical (to the skin) administration and can take the form of liquid, capsules creams, ointments and lotions and can be use alone or in combination with other suitable components in unit-dose or multi-dose containers,

such as ampules and vials as well as a sustained-release formulation (see paragraphs 0098 and 0102-105).

Waugh et al. do not specifically disclose recombinant botulinum toxin (claims 78 and 108), modified botulinum toxin (claim 79), botulinum toxin serotypes B, C, D, E, F, G (claims 82-85, 149 and 150), topically administering the composition to specific locations of the skin (claims 64-73), specific weight ratios (claims 94-96, 105-107) or a specific pH (claim109).

Hanin discloses local administration of botulinum toxins serotypes A, B, C, D, E, F and G to the face (column 4, lines 44-67; column 5, lines 1-2; and column 6, lines 23-24). Moreover, Hanin discloses the use of modified and recombinant botulinum toxin (column 7, lines 54-61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Waugh et al. by substituting the botulinum toxin serotypes, modified or recombinant botulinum toxins as taught by Hanin for the botulinum toxin used in Waugh et al. because Hanin et al. disclose modified and recombinantly made botulinum toxin as well as different serotypes of botulinum toxin can be used for the same intended use. The claim would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the composition to different areas of the skin as recited in claims 64-73 because both Waugh et al. and Hanin disclose topical administration of botulinum toxin

to the skin, which includes the face, axilla, palms of the hands, feet, neck, groin, elbows, arms, knees, buttocks, torso, and pelvis. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. See the recent Board decision *Ex parte Smith,--USPQ2d--,* slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR, 82 USPQ2d* at 1396).

Moreover, regarding the specific weight ratios and pH listed in instant claims 94-96 and 109, MPEP 2144.05 states, “Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re*

Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler,* 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997)."

Limitations such as concentrations or weight ratios and pH of a particular component are being viewed as limitations of optimizing experimental parameters.

One would have had a reasonable expectation, barring evidence to the contrary, that the composition, since all components are known to be used for the same or similar reasons, would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

15. Claim 117 is unpatentable over Waugh et al. (U.S. 2003/0229034 A1; filing date: 6/20/01), Hanin (U.S. Patent No. 6,688,311 B2; filing date: 3/14/02) as applied to claims 51-55, 64-73, 77-116, 118, 149 and 150 above, and further in view of Waugh et al. (U.S. 2004/0220100 A1; filing date: 7/21/00).

The rejected claims are drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent. Subsequent claim 117 requires that the device be a skin patch.

Waugh et al. disclose cosmetic compositions comprising Botulinum toxin (see paragraph 0082) and a backbone having attached positively charged groups such as $(Gly)_{n1}$-$(Arg)_{n2}$, wherein n1 is an integer of from 0 to 20 and from 3 to about 5, and n2 is

an odd integer of from 5 to 25 and about 7 to about 17, or TAT (HIV-TAT) domains. Waugh et al. further disclose that said positively charged backbone and groups are a polypeptide having the formula $(gly)_p$-RGRD-DRRQRR-$(gly)_q$ or $(gly)_p$-YGRKKRRQRRR-$(gly)_q$ (see paragraph 0033 and 0052). Waugh et al. disclose that the positively charged backbone is a polylysine having a molecular weight of 70,000 to 150,000 and 150,000 to 300,000 (see paragraphs 0053). Waugh et al. disclose that the backbone will often be a polymer of repeating units such as a polypropyleneamine and that the composition can comprise and saline as well as a buffer (see paragraphs 0047, 0098 and 0207). Moreover, Waugh et al. disclose that the compositions can be formulated to provide mixtures suitable for topical (to the skin) administration and can take the form of liquid, capsules creams, ointments and lotions and can be use alone or in combination with other suitable components in unit-dose or multi-dose containers, such as ampules and vials as well as a sustained-release formulation (see paragraphs 0098 and 0102-105).

Hanin discloses local administration of botulinum toxins serotypes A, B, C, D, E, F and G to the face (see column 4, lines 44-67; column 5, lines 1-2; and column 6, lines 23-24). Moreover, Hanin discloses the use of modified and recombinant botulinum toxin (see column 7, lines 54-61).

Waugh et al. ('034) and Hanin do not specifically disclose that the botulinum toxin is administered via a skin patch.

Waugh et al. ('100) disclose a method for administering a therapeutically effective amount of a botulinum toxin to the skin or epithelium of the subject via a device such as a skin patch (see paragraphs 0048 and 0076).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Waugh et al. ('034) and Hanin with the skin patch of Waugh et al. ('100) for ease of use, but also because "it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. See the recent Board decision *Ex parte Smith,--USPQ2d--,* slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR, 82 USPQ2d* at 1396).

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
5/20/10

/Vanessa L. Ford/

Primary Examiner, Art Unit 1645